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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,963	07/10/2001	Claudine Guerin-Marchand	010830-118	8667

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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 05/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/900,963	GUERIN-MARCHAND ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *27-37* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Sequence Compliance Letter*.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 27-30, and 37 drawn to DNA sequences encoding a polypeptide comprising at least one liver stage-specific T-cell epitope of *P. falciparum* Liver Stage Antigen (LSA) from the 3' sequence of the LSA, classified in class 536, subclass 23.7.

II. Claims 27, 31-35, and 37drawn to DNA sequences encoding a polypeptide comprising at least one liver stage-specific T-cell epitope of *P. falciparum* Liver Stage Antigen (LSA) from the 5' sequence of the LSA, classified in class 536, subclass 23.7.

III. Claim 36, drawn to a DNA encoding a polypeptide consisting of the last 279 amino acids of SEQ ID NO: 45, classified in class 530, subclass 350. (It is noted that it is not clear what is being claimed by claim 36 as SEQ ID NO: 45 is not a polypeptide, but is a DNA sequence of 12 nucleotides in length. In view of this, the claim will be treated as distinct invention from those of Groups I and II above for the purposes of this election requirement).

The inventions are distinct, each from the other because of the following reasons:

2. The inventions of Group I-III are directed to related inv. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not

capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, each of the claimed inventions is drawn to a DNA sequence encoding a different antigenic sequence from the P. falciparum pathogen. Because each of the different inventions is drawn to a different antigenic sequence, they represent inventions with materially different designs, and require separate searches of the art for the different sequences. These related inventions are therefore distinct one from another.

Species Election

3. This application contains claims directed to the following patentably distinct species:

For Group I above, the Applicant is further required to elect one of the following species of the claimed invention:

(a) wherein the DNA encodes the polypeptide sequence of SEQ ID NO: 22 (including the sequence of SEQ ID NO: 43, which fully encompasses SEQ ID NO: 22)

(b) wherein the DNA encodes the polypeptide sequence of SEQ ID NO: 21 (including the sequences of SEQ ID NOs: 19, 20, and 43, each of which fully encompasses SEQ ID NO: 21); or

(c) wherein the DNA encodes the polypeptide sequence of SEQ ID NO: 23 (including the sequences of SEQ ID NOs: 19, 20, and 43, each of which fully encompasses SEQ ID NO: 23)

For Group II above, the Applicant is further require to elect embodiments wherein the claimed DNA sequence is:

(A) preceded by one of SEQ ID NOs: 2-18, or

(B) followed by one of SEQ ID NOs: 2-18.

For Group I above, and for either of species (A) or (B) of Group II above, the Applicant is further required to elect one of the species of the claimed invention represented by:

(i) the election of one of SEQ ID NOs: 2-18; and

(ii) the election of one of the two amino acids for each of X_1, X_2, X_3, and X_4 as identified in (e.g.) claim 30.

The species are independent or distinct for the following reasons:

Species (a)-(c) of Group I and the various species embodied by the elections of (i) and (ii) for Group I, and the species (A) and (B) of Group II, are directed to related peptides. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, each of the indicated species represents a distinct antigenic sequence. Since each separate sequence both requires a different search, and has a materially different design, the different sequences represent related but distinct inventions.

Species (A) and (B) also represent related but distinct species. In this case, the different species represent peptides with materially different designs in that the various regions of the claimed sequences have different structural relationships with each other. As such different constructions require separate searches, and are materially different in that the claimed sequences have different structures from each other, the different species are distinct.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 27 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Examiner's Notes

4. Claim 32 reads on a DNA sequence encoding "the first 153 amino acids of the amino acid sequence of SEQ ID NO: 37." However, it is noted that SEQ ID NO: 37 is a DNA sequence.

Thus, while the claim has been read as reading on a DNA sequence encoding the first 153 amino acids encoded by this sequence for the purposes of the restriction requirement above; should the Group including this claim be elected, it will be rejected as indefinite.

5. It is noted that both of the sequences SEQ ID NO: 43 and 47 referred to in claim 28 are identical in the sequence listing. Thus, the two sequences are treated as identical for the purposes of this election requirement. However, if it was intended that these sequences vary one from the other, and if Group I above is elected, the Applicant will be required to elect one of the two sequences as a distinct species of the claimed invention as different DNA sequences require separate searches and represent materially different structural compositions.

Sequence Compliance

6. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Conclusion

7. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. It is noted that some of the restrictions requirements made above fall within the scope of PTO Linking claim practice. In accordance with this practice as described in MPEP 809.03, linking claims will be considered with the elected invention. If the elected invention is found allowable, the linking claim will also be examined. If no substantive rejection is found for the linking claim, the restriction among the Groups it comprises will be withdrawn.

In the instant case, claim 27 is considered to be a linking claim to at least the inventions of Groups I and II.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas 5/8/06
Patent Examiner

Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below.

This application contains several disclosures of sequences in the specification. See e.g., pp. 9 (referring to the first 153 amino acids of the sequence of figure 7), 11 (referring to the sequences of shown in several of the figures), 29 (referring to the sequence of Figure 1), and claim 31 (referring to the sequence of Figure 7). However, the specification does not identify each of these sequences by the sequence identifier assigned to them in the sequence listing as required by 37 CFR 1.821(d). The examiner would like to bring the applicant's attention to the following excerpt from MPEP §2422.03:

> 37 CFR 1.821(d) requires the use of the assigned sequence identifier in all instances where the description or claims of a patent application discuss sequences regardless of whether a given sequence is also embedded in the text of the description or claims of an application. This requirement is also intended to permit references, in both the description and claims, to sequences set forth in the "Sequence Listing" by the use of assigned sequence identifiers without repeating the sequence in the text of the description or claims. Sequence identifiers can also be used to discuss and/or claim parts or fragments of a properly presented sequence. For example, language such as "residues 14 to 243 of SEQ ID NO:23" is permissible and the fragment need not be separately presented in the "Sequence Listing." Where a sequence is embedded in the text of an application, it must be presented in a manner that complies with the requirements of the sequence rules.

The applicant is therefore required to amend the specification to comply with 37 CFR 1.821(d).

2. Applicant is given ONE MONTH, or THIRTY DAYS, whichever is longer, from the mailing date of this letter within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for reply beyond the SIX MONTH statutory period. Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

5/18/06